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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/544,897

02/02/2006

Ralf Dunkel

CS-8582/LeA 36,354

6478

34469

7590

12/16/2008

BAYER CROPSCIENCE LP

Patent Department

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EXAMINER

HAVLIN, ROBERT H

ART UNIT

PAPER NUMBER

1626

MAIL DATE

DELIVERY MODE

12/16/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/544,897	Applicant(s) DUNKEL ET AL.	
	Examiner ROBERT HAVLIN	Art Unit 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 October 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19-22, 28 and 33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19-22, 28 and 33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

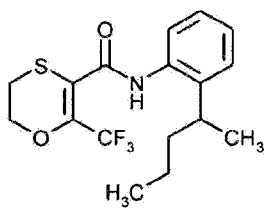
DETAILED ACTION

Status of the claims: Claims 19-22, 28, and 33 are currently pending. Claims 27, and 32 were cancelled.

Priority: This application is a 371 of PCT/EP04/01053, filed on February 5, 2004 and claims benefit under 35 U.S.C. 119(a)-(d) to foreign applications Germany 10306244.0, filed February 14, 2003 and Germany 10321270.1, filed May 13, 2003.

Restriction: Applicant previously elected group I (claims 19-26, 28, 31-33, drawn to compounds of formulae I, IV, VI, and VIII).

Applicant previously elected the species # 39 (of the amended specification) of



the formula

(where Z=1-methylbutyl).

In accordance with the election of species, no generic claim was allowable, therefore the scope of the claims were restricted to the elected species only. Thus subject matter not reading on the elected species is held withdrawn until a generic claim is found allowable. As a result, because claims 27, and 32 do not read on the elected species, they are withdrawn in their entirety.

Declarations: The declaration of Voerste and Wachendorff-Neumann both filed on 10/2/08 filed under 37 CFR 1.132 are insufficient to overcome the rejection of claims 19-22, 28, and 33 based upon 35 USC 103(a) as set forth in the last Office action because: the applicants have failed to meet their burden demonstrating "that the differences are in fact unexpected and unobvious and of both statistical and practical significance." Ex

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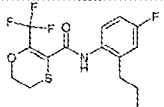
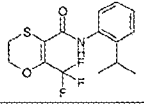
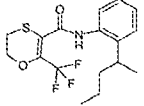
parte Gelles, 22 USPQ2d 1318, 1319 (BPAI 1992). The declarations provide a side-by-side comparison with the prior art compound and the elected species, however, the methodology used does not appear to conform to acceptable scientific principles concerning measuring the efficacy of a chemical agent for treating plants.

First and foremost, there is no error analysis provided. Error analysis on data is the single most significant element of a measurement attempting to use the scientific method. Therefore, this fact alone precludes any determination of whether the results could be deemed “unexpected” or are they just statistical aberrations.

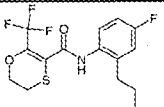
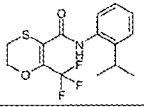
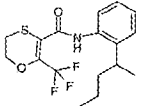
Second, the data provided in the 10/2/08 declaration of Voerste (“V-Oct”) appears inconsistent with the Wachendorff-Neumann 132 declaration filed on 2/25/08 (“WN-Feb”). The data provided is as follows:

Voerste 132 declaration (filed 10/2/08):

Sphaerotheca test (cucumber) / preventive

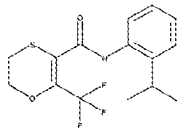
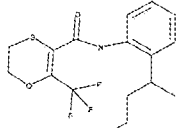
Active compound <u>Known from Hahn et al.:</u>	Rate of application of active compound in ppm	Efficacy in %
	500	0
Compound 53 	500	0
<u>According to the invention:</u>		
Ex. 39 	500	94

Alternaria test (tomato) / preventive

Active compound <u>Known from Hahn et al.:</u>	Rate of application of active compound in ppm	Efficacy in %
	500	0
Compound 53 	500	0
<u>According to the invention:</u>		
Ex. 39 	500	95

Wachendorff-Neumann 132 declaration (10/2/08):

Uromyces test (Bean) / protective

Active compound	Rate of application of active compound in g/ha	Efficacy in %
Known from Hahn et al.		
Compound 53 	100	10
According to the invention:		
Example 39 	100	95

And WN-Feb:

Table A: Sphaerotheca test (cucumbers) / protective

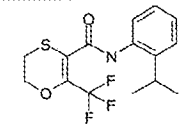
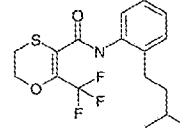
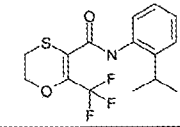
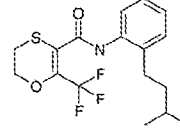
Active compound	Rate of application of active compound in ppm	Efficacy in %
Comp. 53 of Hahn et al. 	100	10
According to the invention:		
Comp. 102 of CS-8582/ LeA 36354 	100	98

Table B: Venturia test (apples) / protective

Active compound	Rate of application of active compound in ppm	Efficacy in %
Comp. 53 of Hahn et al. 	100	57
According to the invention:		
Comp. 102 of CS-8582/ LeA 36354 	100	100

The conflicting measurements appear in Comp. 53 in Sphaerotheca test of WN-Feb and Compound 53 Sphaerotheca test of V-Oct. In the former the result was 10% efficacy while in the latter it was 0% efficacy. Given that the test was for the same compound on the same substrate, these inconsistent results suggest a statistical problem in the measurements. Keeping in mind that the applicant has the burden of explaining the proffered data, this result requires an explanation that is consistent with the scientific method. See MPEP § 716.02(b).

Therefore, because the data presented has questionable statistical significance (lacking controls, error analysis, etc.), the declarations are not found persuasive to overcome the obviousness rejections.

RESPONSE TO APPLICANT REMARKS

Double Patenting

1. Claims 19-22 and 28 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 11-14, and 17 of copending Application No. 10/576153.

Applicant argues that the trifluoromethyl group is sufficiently distinguishable from the subject matter of '153 which only has a methyl. The examiner finds this argument persuasive and **the rejection is withdrawn**.

Claim Rejections - 35 USC § 112

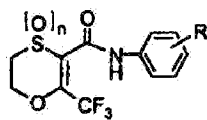
2. Claims 19-22 and 28 were rejected under 35 USC 112 1st paragraph as failing to comply with the written description requirement. Applicant's argument that the 103 specific compounds and the original disclosure are sufficient to satisfy the written description requirement. The examiner has considered the argument and found it persuasive. Therefore, this **rejection is withdrawn**.

Claim Rejections - 35 USC § 103

3. Claims 19-22, 28, and 33 were rejected under 35 U.S.C. 103(a) as being unpatentable over Hahn et al. (Han'guk Nonghwa Hakhoechi (2001), 44(3), p. 191-196). Applicant argues that Hahn does not suggest the claimed compounds because (1) it does not teach Z as Z2 or Z4 (to which the examiner agrees) and (2) it does not teach

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or suggest Z as Z3. As the examiner pointed out in the prior office action, Hahn teaches



“R” alkyl homologues of the structure

each of which is measured for

bacteriocidal activity, thereby suggesting modifications of the R alkyl group would also continue to show the demonstrated activity. In addition, as discussed above, because the 132 declarations were not found persuasive due to scientific method deficiencies, there was no unexpected result shown, thus the argument of non-obviousness is not found persuasive. Therefore **the rejection is maintained.**

Conclusion

The claims are not in condition for allowance. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROBERT HAVLIN whose telephone number is

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(571)272-9066. The examiner can normally be reached on Mon. - Fri., 7:30am-5pm EST.

If attempts to reach the examiner by telephone are unsuccessful the examiner's supervisor, Joe McKane can be reached at (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Robert Havlin/
Examiner, Art Unit 1626

/Rebecca L Anderson/
Primary Examiner, Art Unit 1626